

NOV 28 2001

Attachment I
510(K) Summary
BASIC Dental Implant System Implant

K013252

This 510(K) Summary of safety and effectiveness for the BASIC Dental Implant System Implant is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: BASIC Dental Implant Systems, Inc.

Address: 3321 Columbia NE
Albuquerque, New Mexico 87107
USA

Contact Person: Dan Blacklock, Vice-President

Telephone / Fax / Email 505.881.1376 – Phone
505.884.1923 – Fax

Preparation Date: October 30, 2001

Device Trade Name: BASIC Dental Implant System Implant

Common Name: Dental implant

Classification: DZE

Legally Marketed Predicate Device: BASIC Dental Implant System
K960868

Description of the Implant: The BASIC Dental Implant is an endosseous dental implant.

Intended use: The Implant for dental purposes, used to replace missing dental organs (teeth). The Implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the Implant receives a post, which has a stem, and is adapted to carry dental suprastructures (false teeth).

Performance Data: None

Results of Clinical Study: None

Conclusion: The BASIC dental implant is substantially equivalent to previous BASIC dental implants in commercial distribution.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 28 2001

Mr. Dan Blacklock
Vice President
Basic Dental Implant Systems, Incorporated
3321 Columbia, N.E.
Albuquerque, New Mexico 87107-2001

Re: K013682

Trade/Device Name: Modification To Basic Dental Implant System
Regulation Number: 872.3640
Regulation Name: Dental Implant
Regulatory Class: III
Product Code: DZE
Dated: October 30, 2001
Received: November 7, 2001

Dear Mr. Blacklock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

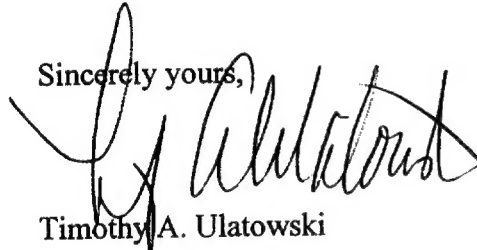
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K013682

Device Name: BASIC Dental Implant System Dental Implant

Indications for Use:

The Implant for dental purposes, used to replace missing dental organs (teeth). The Implant is self-tapping (threads) and is screwed into a pilot bore formed in the jawbone. Upon healing, the Implant receives a post, which has a stem, and is adapted to carry dental suprastructures (false teeth).

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(per 21 CFR 801.109)

OR

Over-the-Counter Use

Susan Russo

(Division Sign-Off)

Division of Dental, Infection Control,

and General Hospital Devices

510(k) Number K013682